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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.            | CONFIRMATION NO. |
|--|-------------|----------------------|--------------------------------|------------------|
| 09/802,668   | 03/09/2001  | Steven L. Roberts    | PHRM-0319                      | 3061             |
| 34135 7590 03/31/2005<br>COZEN O'CONNOR, P.C.<br>1900 MARKET STREET<br>PHILADELPHIA, PA 19103-3508 |             |                      | EXAMINER<br>CHERNYSHEV, OLGA N |                  |
|  |             |                      | ART UNIT<br>1646               | PAPER NUMBER     |
| DATE MAILED: 03/31/2005  |             |                      |                                |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/802,668

Applicant(s)

ROBERDS ET AL.

Examiner

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-123 is/are pending in the application.
- 4a) Of the above claim(s) 1-94 and 97-116 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 95, 96 and 117-123 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 18, 2004 has been entered.

***Response to Amendment***

2. Claims 95, 96 and 117 have been amended and claims 118-123 have been added as requested in the amendment filed on October 18, 2004. Claims 1-123 are pending in the instant application.

3. Applicant is reminded that this application contains claims 1-94 and 97-116 drawn to an invention nonelected with traverse in Paper No. 14. A complete reply to the final rejection must have included cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

4. Claims 95, 96 and 117-123 are under examination in the instant office action.

5. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

7. Applicant's arguments filed on October 18, 2005 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

***Claim Rejections - 35 USC § 101***

8. Claims 95, 96 and 117-123 are rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for reasons of record as applied to claims 95, 96 and 117 in previous office actions of record. Briefly, the instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. Because the instant application does not disclose the biological role of this protein or its significance, an antibody to the protein cannot be considered particularly useful.

At pages 23 and 24 of the Response, Applicant reviews case law pertaining to the utility requirements and submits that "[t]he identity of SEQ ID NO: 105 as a human ion channel receptor provides support for the utility of the present invention". Applicant further refers to certain parts of the instant specification, which allegedly describe *in vitro* tests that "provide a way to overcome a §101 rejection" (middle at page 23 of the Response). Applicant's review of the issue of utility, the case law that has been cited and the holding that is found in that case law is not disputed. The only point of disagreement appears to be the interpretation of what constitutes a specific, substantial and credible utility.

As fully explained previously, the utility of the instant claimed antibodies is based on practical utility of the instant disclosed polypeptide of SEQ ID NO: 105. It is clear from the instant specification that at the time of filing the biological significance of this specific

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polypeptide of SEQ ID NO: 105 or its usefulness with regards to a particular disease, disorder or physiological process was not known. The only information pertained to physiological role of a polypeptide of SEQ ID NO: 105 as disclosed in the instant specification is limited to assertion that it represents a human ion channel. One skilled in the art readily appreciates that any cell membrane comprises a plurality of ion channels and, as explained earlier, there is little doubt that, after complete characterization, this particular human ion channel of SEQ ID NO: 105 may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediate obvious or fully disclosed "real world" utility.

Furthermore, with respect to Applicant's reference to pages 52, 54 and 57-58 of the instant specification, the Examiner failed to find support for asserted specific and substantial credible utility at the above noted passages. The text on pages 52-58 appears to be limited to description of kits comprising antibodies as well as information of potential methods of using antibodies in general, and, therefore, does not add any specific information regarding practical utility of the claimed invention.

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At bottom of page 23 continuing to page 24, Applicant argues that the USPTO issued numerous patents to antibodies directed to specific amino acid sequences. Applicant is advised that the prosecution of one patent application does not affect the prosecution of an unrelated application, see *In re Wertheim*, 541 F.2d 257, 264, 191 USPQ 90, 97 (CCPA 1976) (holding that “[I]t is immaterial in *ex parte* prosecution whether the same or similar claims have been allowed to others”). Accordingly, Applicant’s arguments are not persuasive.

Therefore, for reasons fully explained earlier and reasons above, the instant rejection is maintained.

### ***Claim Rejections - 35 USC § 112***

9. Claims 95, 96 and 117-123 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 95, 96 and 117-123 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claims 95, 96 and 117-123 are vague and indefinite in so far as they employ the term “5HT3E” as a limitation. Applicant is advised that without a reference to a precise amino acid

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sequence identified by a proper SEQ ID NO: one cannot determine the metes and bounds of “5HT3E” or “5HT3E epitope”. Moreover, because the instant specification does not identify that property or combination of properties which is unique to and, therefore, definitive of a “5HT3E”, an artisan cannot determine if a compound which meets all of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation.

12. Claims 95 and 96 are vague and ambiguous for recitation “fragment thereof”. It is not clear and cannot be determined from the claims or the instant specification if “fragment” of an antibody or polypeptide of SEQ ID NO: 105 is intended by the claims. Clarification is required.

13. Claim 96 is further indefinite for recitation “a unique 5HT3E epitope”. It is not obvious how to distinguish “a unique 5HT3E epitope” from “a 5HT3E epitope”, and, therefore, the metes and bounds of the claimed subject matter cannot be positively determined.

### ***Conclusion***

14. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Anthony C. Caputa can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (571) 273-0870. Official papers should NOT be faxed to (571) 273-0870.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Olga N. Chernyshev, Ph.D.  
Primary Examiner  
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March 28, 2005